

# Gender Knees: Science or Marketing?

Although the necessity for a gender specific implant is certainly debatable, the question will be, “Is Zimmer’s gender solutions knee a worthwhile technology or just an attempt to correct existing design flaws?” This paper will explore the design features that make the Zimmer knee supposedly “gender friendly,” and how Smith & Nephew offers superior products for both male as well as female patients.

## What are the design changes to the gender knee?

Zimmer has claimed several design features of their gender knee will improve the overall success of a total knee replacement in a female patient. Those design changes include: 1) a decreased aspect ratio (narrowed component); 2) thinner anterior flange and 3) lateralized trochlear groove.

### Sizing (Decreased Aspect Ratio)

A major design feature that is being marketed as a “female friendly” is the decrease of the femoral component’s aspect ratio. In simple terms an aspect ratio is the ratio that is found when comparing the A/P length to the M/L width of a femoral component. When measuring to determine the appropriate size implant for the patient, the surgeon will usually measure both anterior to posterior and medial to lateral on the femur. Women are typically narrower medial to lateral. Surgeons use the anterior to posterior measurement to choose which implant size, which is important for attaining the maximum flexion of the knee. Until the release of their LPS flex, Zimmer was known to have wide femoral components. (Exhibit 1) The gender femoral continues to decrease their overall aspect ratio. One very important system feature was still overlooked. For a surgeon to have the ability to custom fit an implant to any patient, the most important factor is the amount of sizes that a knee system can offer. Zimmer NexGen offers eight femoral sizes, Stryker Triathlon offers eight sizes and GENESIS® II offers nine sizes.

### Risk of a narrow femoral component

While a narrower femoral component design might fit the anatomy of women, there are risks involved. When redesigning the femoral component to become gender friendly, Zimmer did not change the design of the polyethylene insert. Therefore a thinner condyle will now interact with a polyethylene insert that was originally designed for wider femoral condyles. With the design of a narrower femoral component, there will be a decrease in the contact area between the component and polyethylene.

Stress = Load/Area

A decrease in contact area will directly increase the associated contact stresses. Systems like the GENESIS II Total Knee System have increased contact area which translates into decreased contact stresses. Laboratory tests were conducted to identify the amount of applied load that resulted in contact stresses above the yield strength of the polyethylene. Although the new gender femoral was unavailable for testing, the PFC® Sigma femoral was tested, as the PFC® Sigma femoral has narrow femoral condyles, similar to Zimmer’s gender knee. The PFC Sigma had a total of 225mm<sup>2</sup> of contact area. The test showed that 18.2% (41mm<sup>2</sup>) of that contact area was above the yield strength of the polyethylene. This was caused by the increased contact stresses of a narrower femoral condyle. When the GENESIS II® Total Knee System was put through the same test, it showed a total of 285mm<sup>2</sup> of

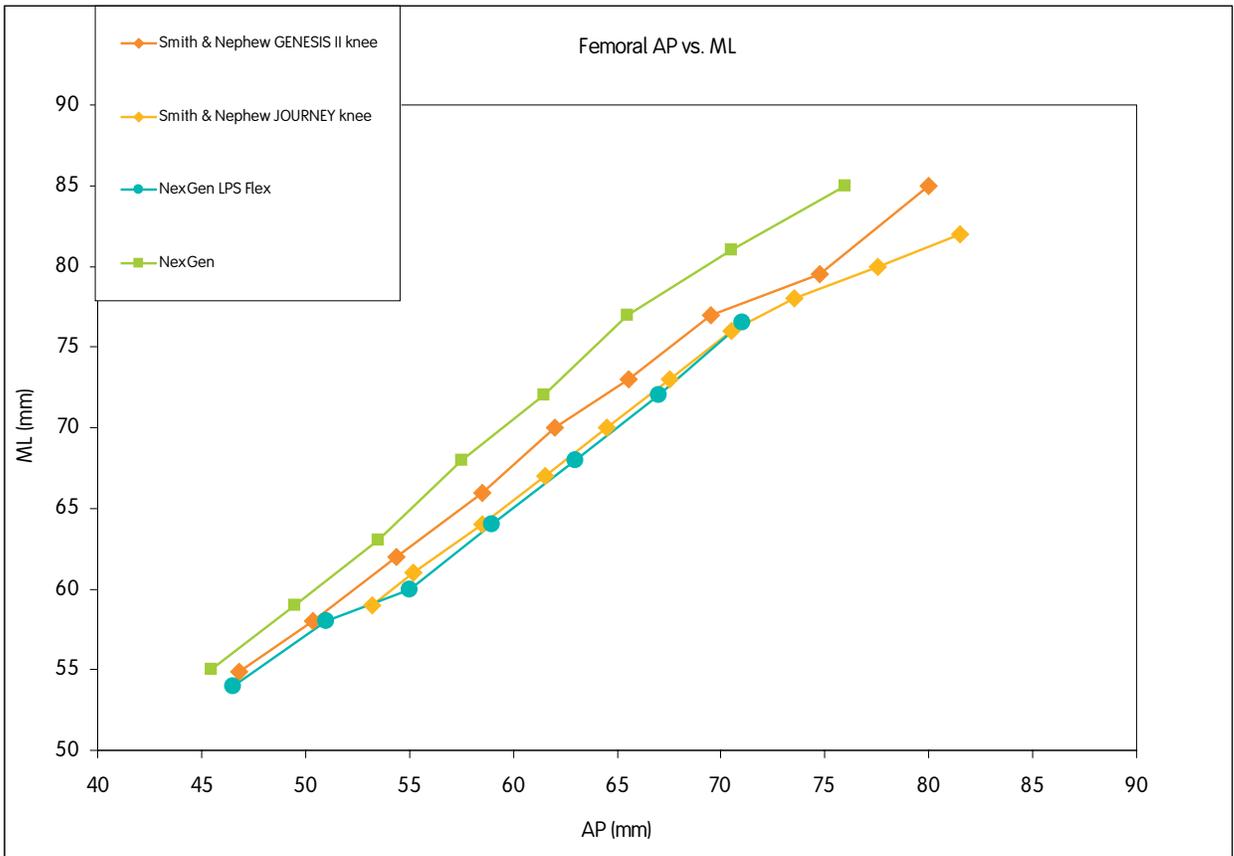


Exhibit 1

contact area. The test then showed .017% (5mm<sup>2</sup>) of polyethylene had stresses over the yield limit.<sup>1</sup> This extremely low amount of contact stress is achieved by having highly congruent femoral condyles, thus increasing the longevity of the polyethylene.

**Sizing the GENESIS II Total Knee System**

During the design process of the GENESIS II Total Knee System, femoral sizing that would support both the female and male patient was developed. Femoral sizing for GENESIS II was determined by analyzing measurements collected during over 500 total knee arthroplasty procedures. A/P and M/L dimensions were collected from a diverse population consisting of both males and females from various parts of the world. In a recent intraoperative study that was used to help design the size offerings for the JOURNEY<sup>®</sup> BCS Knee System, surgeons were asked to collect data on a number of sizing measurements, one of which was to determine what

size femoral component was going in with which gender of patient. A GENESIS II femoral component was used in every patient. The results show that 100% of the female patients received a GENESIS II femoral size 5 or smaller. This shows that the data that was used to engineer the different sizing options of GENESIS II was extremely accurate. For the past 10 years the sizing options of GENESIS II have resulted in successful total knee replacements. In a recent five-year study published by Dr. Richard S. Laskin, 100 consecutive knees implanted into both genders using the GENESIS II Total Knee System had a survivorship of 98% and 100% showed good to excellent results. These results show that the sizing options of the GENESIS II Total Knee System will produce excellent results in both males and female patients.<sup>2</sup>

### Thinner Anterior Flange

Zimmer claims that by decreasing or thinning the thickness of the anterior flange on their gender knee that they will accomplish two things; 1) help prevent the “bulky” feeling a woman might feel after a TKA and 2) help prevent anterior knee pain. The thinning of the anterior flange to improve TKA results has no history in any past publications. There is also no rating system to test the “bulky” feeling that a patient might feel after a TKA. Having a thin anterior flange is not a bad design, but other factors are much more important when creating a total knee system.

One of the most important features of a femoral component is the shape and position of the component’s articular surface. This determines interaction with the rest of the knee. It can be argued that an extremely thick anterior flange with proper geometry and position would produce a better outcome than a thinner anterior flange with poor geometry and position. The thickness of the anterior flange is not as important as the articular surface geometry and position of the component in relation to the original femoral anatomy.

### Lateralized Trochlar Groove

It has been shown that the width of female hips is generally wider than males. The angle between the knee and pelvis is the angle in which the patella is going to track throughout range of motion. When creating the Gender Femoral, Zimmer increased the angle of the trochlear groove. Zimmer claims that this slight shift is going to help prevent overstuffing of the patella, which will lead to improved postoperative range of motion. The fact that this wider groove angle can help prevent overstuffing has never been completely proven. The angle of the groove is not the most important factor in promoting deep flexion, it is the groove itself. When the gender femoral has to be externally rotated, the proximal patella is lateralized but distally the groove is medialized. The issue that can be found with this design is that during ROM this groove can increase the risk of the patella tracking to the midline too early. By the time ROM has reached deep flexion, the patella is in increased risk of crossing the midline. If the patella crosses the midline in deep flexion (where the stresses are greatest) it can promote excessive wear and deformation caused by edge loading. Edge loading of the patella has also been discussed as a cause of anterior knee pain.

The GENESIS<sup>®</sup> II femoral component was engineered to have an S-Curve trochlear groove. With GENESIS II, the trochlear groove is lateralized by design. In extension, the patella sits naturally. Throughout ROM, the S-Curve gently funnels the patella towards the midline. (Exhibit 2)

Exhibit 2



## Design issues, left uncorrected

A question that has been raised throughout this whitepaper is that in creating the gender optimized knee, Zimmer is simply trying to correct the design features of their previous knee systems. In their attempt however, they overlooked a few of the issues their current knee systems have been accused of having.

### Tibial Baseplate Coverage

In their attempt to create a truly gender optimized knee design, Zimmer has overlooked a major portion of the total knee replacement process. If a knee system's goal is to be anatomic, knee components should be designed to replicate the human anatomy. Zimmer has made no change to the tibial baseplate portion of their NexGen Gender Solutions Knee System. Their symmetrical tibial baseplate does not match the anatomy of a total knee patient. Some believe that maximization of tibial coverage is vital to the long term success of a total knee replacement. In studies by Bindeglass et al.<sup>3</sup> and Brandon et al.<sup>4</sup> it was believed that 85% tibial coverage is sufficient for a TKR. When the GENESIS<sup>®</sup> II tibial baseplate was designed, it was based on the anatomy of both males and females trying to maximize tibial coverage for both sexes. The design of the GENESIS II tibial baseplate is asymmetric, the shape of both male and female anatomy. A study by Westrich et al.<sup>5</sup> showed that the GENESIS II tibial baseplate produced an average tibial coverage of  $90.85 \pm 3.08\%$ , far greater than the suggested minimal amount. In this same study a tibial baseplate produced by Zimmer showed an average tibial coverage of  $80.07 \pm 4.79\%$ , much less than the suggested minimal amount. When using a symmetric tibial baseplate a surgeon is forced to make a choice between two, non-optimal situations. To maximize tibial coverage a surgeon will need to select a symmetric baseplate that will overhang posterior-laterally. (Exhibit 3) The other option is to prevent overhang by downsizing the baseplate. This will leave the posterior-medial corner of the tibia exposed. (Exhibit 4) By having an asymmetric tibial baseplate of the GENESIS II system maximizes tibial coverage on all areas of the tibia. (Exhibit 5) All in all, Zimmer's attempt to create a gender optimized knee system addresses only part of the problem. Their tibial baseplate is symmetric, the design is not based on what is found in the human anatomy, and therefore they will always sacrifice tibial coverage.



Exhibit 3



Exhibit 4



Exhibit 5

### Posterior-Stabilized Dislocation

The design of the NexGen LPS-flex suggests there could be an increase in posterior dislocation. To promote strength in deep flexion, the cam of the femoral component that engages the polyethylene insert post was placed high on the femoral condyles. In extension however the cam is higher than the top of the post (Exhibit 6). Therefore the chances of posterior dislocation may be increased. The design of the GENESIS<sup>®</sup> II cam is placed lower of the condyles (Exhibit 7), giving the knee increased stability in full extension.

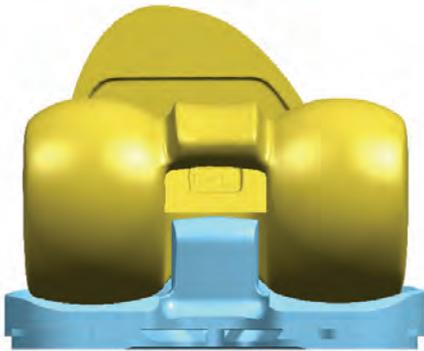


Exhibit 6

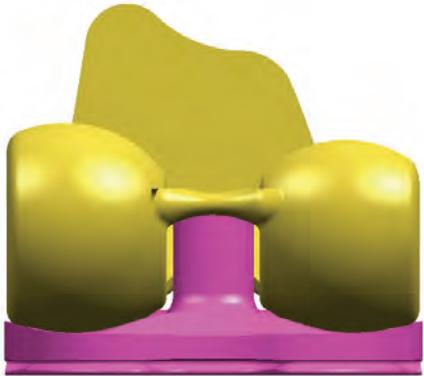


Exhibit 7

### Anterior Post Impingement

A major concern of any posterior-stabilized knee design is polyethylene post wear. To solve that issue the GENESIS II polyethylene post was moved posteriorly. A more posterior post also allows for hyperextension, a normal movement of the knee. In the NexGen LPS-flex design the post is more anterior than the GENESIS II.<sup>6</sup> An analysis of the NexGen LPS-flex post was performed (Exhibit 8). As you can see, there are increased stresses on the anterior of the post in full extension. Increased stresses can almost always lead to increased wear. The anterior post will also prevent hyperextension of the knee.

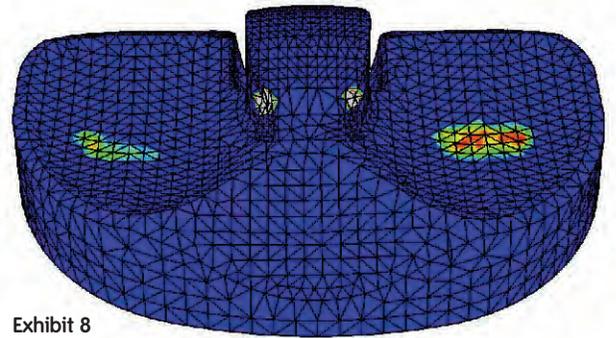


Exhibit 8

## Increased Bone Resection

When comparing the deep flexion capabilities of the Gender Femoral and GENESIS<sup>®</sup> II Total Knee System, they both attain a high amount of flexion. The gender knee can support up to 155° of flexion, same as GENESIS II. Although the flexion is equivalent, what is important is how the deep flexion is accomplished. To create a higher amount of flexion within the GENESIS II system, our engineers studied our already flexion friendly standard cruciate-retaining and posterior-stabilized inserts, put them through a range of motion and found where the points of impingement were located. The next step was to relieve those points of impingement. The cruciate-retaining deep flex insert has a chamfered anterior to minimize patellar tendon/implant impingement, a deepened PCL notch to allow for smoother PCL tracking and a lowered posterior lip to help minimize cortical impingement. The posterior-stabilized high flex insert also incorporates the chamfered anterior as well as the lowered posterior lip, but it also has a chamfered anterior post. This is designed to eliminate patellar component impingement, but has equal fatigue strength as the standard PS insert.

The Gender Knee design is based off of the NexGen LPS flex. The LPS flex femoral can achieve 155° of flexion but it does it in a different way. To help promote deep flexion, you must take an additional 2-3mm of bone off posteriorly. This is done to bring the posterior condyles into a tighter radius. The issue is simple, why should a surgeon sacrifice additional bone for flexion that can be achieved by simply switching a polyethylene insert.

## Conclusion

The necessity for gender specific implants is, and will remain a topic for debate. By creating the gender specific knee is Zimmer creating a new technology or are they trying to correct the design features of their past total knee systems? Either way we have shown that there are design features within the gender knee system, which still may be a cause for concern. To make a knee system based on the shape of a female, why are the tibial baseplates still symmetric? It has been shown that the anatomy of the female tibia is asymmetric. No correction to the posterior stabilized design was made, the risks of posterior dislocation and damage caused by anterior impingement still remain.

The GENESIS II Total Knee System was designed using the anatomy of both men and women. The studies used in sizing the femoral components used both male and female cadavers. The tibial baseplate of the GENESIS II system is asymmetric, to match the anatomy of both men and women. Finally, the GENESIS II Total Knee System is a proven knee system with successful mid-term results for both men and women.

## References

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## Orthopaedic Reconstruction

Smith & Nephew Inc.  
1450 Brooks Road  
Memphis, TN 38116  
USA

[www.smith-nephew.com](http://www.smith-nephew.com)

Telephone: 1-901-396-2121  
Information: 1-800-821-5700  
Orders and Inquiries: 1-800-238-7538